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K964557

ReSound® BT4 Personal Hearing System™

SUMMARY OF SAFETY AND EFFECTIVENESS

Substantial equivalence for the ReSound® BT4 Personal Hearing System™ to the predicate device, the ReSound® Personal Hearing System BT (marketed as the BT2), 510(k) No. K912665/A, July 24, 1991, is based on the following:

- This air-conduction behind-the-ear hearing instrument, intended to amplify sound pressure waves and transmit the signal to the external ear through the medium of air, is designed to compensate for hearing losses from mild to severe.
- The device is powered by a standard hearing aid battery (type 13).
- The device is manufactured and delivered completely assembled to the hearing aid dispenser using materials and techniques widely used by other manufacturers of hearing devices.
- The intended use, performance specifications, functions and operations of the ReSound® BT4 Personal Hearing System™ are essentially identical to that described in the 510(k) Premarket Notification for the ReSound® Personal Hearing System BT.
- The ability to program digitally the fitting parameters of the hearing device is the same as in the ReSound® Personal Hearing System BT, as is the ability to change the characteristics of the sound processing and adjust the volume via an ultrasound remote control. The ReSound® BT4 Personal Hearing System™ and the predicate device have the ability to retain two programs in memory.
- The operation and functioning of the DAI option is identical to that offered by other hearing aid manufacturers.